

### **REMARKS**

The present response is submitted in reply to the Office action issued on December 2, 2008. Claims 1-21 and 27-43 are pending in this application. Claims 1-21 and 27-42 are rejected and claim 43 is objected to. By the present response, claims 1-21 and 27-43 have been canceled and claims 44-71 have been newly added, as discussed below.

The Applicant wishes to thank the Examiner for concluding that claim 43 contains allowable subject matter and would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. In view of this, claim 43 has been amended herein (now new claim 44) to be placed into independent form and to incorporate subject matter from previous independent claims 1 and 41. The details of the newly added claims are discussed below. No new matter has been added. Reconsideration is respectfully requested in light of the amendments being made hereby and of the following remarks.

#### **Rejection of claims 1, 2, 5-12, 15-18, 20, 21, 29-31 and 33-41 under 35 U.S.C. 102(a) and Rejection of claims 1-21, 27-42 under 35 U.S.C. 103(a)**

Claims 1, 2, 5-12, 15-18, 20, 21, 29-31 and 33-41 have been rejected under 35 U.S.C. 102(a) as being anticipated by WO 02/02085 (corresponding to U.S. Publication No. 2004/0028732) (Falkenhausen, et al.). The Examiner essentially concludes that Falkenhausen, et al. disclose every limitation recited in the aforementioned claims. In particular, the Examiner states that Falkenhausen, et al. teach a rapidly disintegrating sheet or wafer dosage form having a thickness of between 0.1-5 mm, the dosage form comprising matrix-forming polymers, active ingredients, and a carbon dioxide gas

forming agent. The Examiner further states that the polymers include cellulosic polymers, and water-soluble polysaccharide. Lastly, the Examiner states that the dosage form further comprises eucalyptus oil, peppermint oil, flavor, sweetener, other additives and foams, such as propylene glycol and that the dosage form disintegrates in the oral cavity in the range from 10-30 seconds. The Examiner does note that Falkenhausen, et al. is silent with respect to the density of the dosage form, but that the Applicant has the burden of showing that the dosage form of Falkenhausen, et al. does not exhibit the claimed properties since Falkenhausen, et al. teach the same dosage form using the same dosage structures.

Claims 1-12, 15-21, 27-31 and 33-42 have been rejected as being unpatentable over Falkenhausen, et al. in view of U.S. Publication No. 2003/0091629 (Pather, et al.). The Examiner argues that Falkenhausen, et al. teach every limitation of these claims (as discussed above) but fail to teach the claimed carbon dioxide forming substance. The Examiner notes that Pather, et al. teach an effervescing sublingual buccal dosage form comprising a drug, an additive and an effervescent in an amount of about 5% to about 95%. The Examiner also states that Pather, et al. teach that effervescent includes sodium carbonate and potassium carbonate. The Examiner concludes that it would have been obvious to one skilled in the art to modify the rapidly disintegrating dosage of Falkenhausen, et al. to include the carbon dioxide forming substances such as sodium carbonate in an amount in view of the teaching of Pather, et al. for arriving at the presently claimed invention. The Examiner also states that Falkenhausen, et al. fail to teach the amount of water-soluble polymer, but that the differences in concentration will not support the patentability absent evidence indicating such concentration is critical. In

this regard, the Examiner concludes that it would have been obvious for one skilled in the art to select an amount of matrix-forming polymer that falls within the claimed range since Falkenhausen, et al. teach the desirability to use the same matrix-forming polymer to obtain the same film shape dosage form having the same disintegrating time.

Claims 13, 14 and 32 have been rejected as being unpatentable over Falkenhausen, et al. in view of U.S. Publication No. 2007/0122455 (Myers, et al.). The Examiner argues that Falkenhausen, et al. teach every limitation of these claims (as discussed earlier) except for ethyl cellulose as the film-forming polymer. The Examiner relies on Myers, et al. and argues that the latter reference teaches a uniform film for rapid-dissolve dosage form comprising ethyl cellulose as a matrix-forming polymer, as well as the uniform film comprising a mucoadhesive layer. The Examiner concludes that it would have been obvious to one skilled in the art to modify the rapidly disintegrating dosage of Falkenhausen, et al. using ethyl cellulose as a film-forming polymer in view of Myers, et al. since Myers, et al. teach using ethyl cellulose in rapid-dissolve film-shaped dosage form is known in the art and since Falkenhausen, et al. teach the desirability for using cellulosic film-forming polymers.

As noted above, the Examiner has concluded that claim 43 contains allowable subject matter and would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims (Office action dated December 2, 2008, page 5). Accordingly, the Applicant has canceled claims 1-21 and 27-43 and submits herewith a new set of claims 44-71. New independent claim 44 is based on the allowable subject matter of claim 43 and includes many of the limitations of independent claims 1 and 41. The new dependent claims are based on the previously

pending dependent claims as set forth below for ease of reference:

Claim 45 (former claim 3); Claim 46 (former claim 4); Claim 47 (former claim 27); Claim 48 (former claim 28); Claim 49 (former claim 5); Claim 50 (former claim 6); Claim 51 (former claim 7); Claim 52 (former claim 10); Claim 53 (former claim 32); Claim 54 (former claim 11); Claim 55 (former claim 13); Claim 56 (former claim 14); Claim 57 (former claim 15); Claim 58 (former claim 33); Claim 59 (former claim 34); Claim 60 (former claim 16); Claim 61 (former claim 35); Claim 62 (former claim 36); Claim 63 (former claim 17); Claim 64 (former claim 18); Claim 65 (former claim 37); Claim 66 (former claim 38); Claim 67 (former claim 19); Claim 68 (former claim 39); Claim 69 (former claim 40); Claim 70 (former claim 20); Claim 71 (former claim 21);

In view of the present amendments, it is submitted that the aforementioned rejections based on the prior art is no longer germane as the prior art fail to teach each and every limitation of the presently claimed invention. Therefore, withdrawal of the present rejections is respectfully requested.

### **Conclusion**

For the foregoing reasons, it is believed that the present application, as amended, is in condition for allowance, and such action is earnestly solicited. Based on the foregoing arguments and the deficiencies of the prior art references, the Applicants strongly urge that the rejections be withdrawn. The Examiner is invited to call the

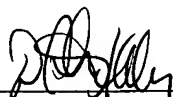
undersigned if there are any remaining issues to be discussed which could expedite the prosecution of the present application.

Respectfully submitted,

Date: \_\_\_\_\_

April 20, 2009

By: \_\_\_\_\_



D. Peter Hochberg  
Reg. No. 24,603

D. Peter Hochberg Co., L.P.A.  
1940 East 6<sup>th</sup> Street, 6<sup>th</sup> Floor  
Cleveland, OH 44114  
(216) 771-3800